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Please find below and/or attached an Office communication concerning this application or proceeding.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/069,691
Filing Date: June 03, 2002
Appellant(s): GILL ET AL.

Craig Bohlken
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5/9/2008 appealing from the Office action mailed 12/12/2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

US Patent No. 5,951,952	CRANE ET AL.	10-1999
US Patent No. 6,200,658	WALTHER ET AL.	3-2001
JP 11-9992	YAMAGUCHI ET AL.	4-1999

DE 29,609,958 U SCHOTT GLASWERKE 10-1996

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crane (US Patent No. 5,951,952) in view of Yamaguchi et al (JP 11-99192) in further view of Schott Glaswerke (DE 29,609,958) or Walther et al (US Patent No. 6,200,658).

Crane et al disclose a method of diagnosing or radioimaging tumor using a metal complexed with an organic ligand. The radiopharmaceutical of Crane et al is 99mTc- or 186/188Re-tertiary butyl isonitrile (see entire document, especially, abstract; column 1, lines 54-61). In addition, Crane et al disclose a kit comprising the metal complex, a solubilization aid, and a reducing agent (column 1, lines 62-67). The diagnostic kit comprises a collection of components in one or more vials which are used by the user in a clinical or pharmacy setting to synthesize the radiopharmaceutical (column 8, lines 3-15). The kit may optional comprise a bacteriostat such as butyl paraben, or other ingredients such as a buffer or stabilization aid. The inclusion of an optional ingredient in the kit frequently improves the ease of synthesis of the radiopharmaceutical (column 5, lines 22-35; column 7, lines 42-46). The purpose of the bacteriostat is to inhibit the growth of bacteria in the diagnostic kit either during its storage before use or after the kit is used to synthesize the radiopharmaceutical (column 8, lines 36-39). The kits may be contained in one or more vials (column 5, lines 38-40). The choice of radionuclides for imaging depend on the use of the radiopharmaceutical (whether the radionuclide is used for therapeutic or diagnostic purposes) (column 5, line 48, through column 6, line 4). Thus, while Crane et al disclose a radiopharmaceutical comprising a complex with an organic ligand and metal and a kit which may comprise one or more vials and a

bacteriostat, the reference fails to disclose that the container (e.g., vial) is silica coating on the inner surface.

Yamaguchi et al disclose containers for radiopharmaceuticals and radiopharmaceutical preparations using the container. The objective of Yamaguchi et al was to develop containers for pharmaceutics which can prevent highly adsorbable radiopharmaceuticals from being adsorbed thereon and provide a clear description of their contents and the amounts thereof (see entire document, especially, page 1; page 3, 'Detailed Description of the Invention'; page 6, paragraph [0008]; page 7, paragraph [0011]). Yamaguchi et al solved the problem by coating the interior surface of a glass container with silica that is used to house radiopharmaceuticals (page 2, entire page; and page 3, claim 4). In claim 5, Yamaguchi et al invention is directed to a radiopharmaceutical preparation which is characterized in that a radiopharmaceutical container (the container is glass) has an interior surface that is coated with silica and filled with an adsorbable radioactive material (page 3, claim 5). Also, it is disclosed in the prior art, radioactive materials are used as tracers for diagnostic imaging in medical fields and that in some instances, a single element is used as the radioactive material and in other instances, label compounds are used which have specific in vivo behavior (page 4, paragraph [0002]. In addition, it is disclosed that detailed method of coating the interior surface of a glass container with silica are known in the art and are commercially available under the name of Silicoat (the containers are made by Fuji Glass Corp.) (pages 7-8, bridging paragraph). It should be noted that while Yamaguchi

et al discloses the use of thallium chloride as the radioactive material, the reference teachings are not limited to thallium chloride.

Walther et al disclose numerous applications for hollow glass bodies made form low melting glass material which require an increase in the chemical resistance of the interior surface of the glass body. In order to avoid a disadvantageous dealkalizing process, the interior surface of the hollow glass body is coated. The interior surface may be coated with SiO2 (silicon dioxide, commonly known as silica) having a predetermined coating thickness according to the required chemical resistance or working conditions for forming the glass body. The coating is advantageously provided by means of a plasma chemical vapor deposition (PCVD) process (see entire document, especially, abstract; column 4, lines 39-44; and columns 4-5, bridging paragraph)

Schott Glaswerke disclose glass containers useful for storing pharmaceuticals and diagnostic solutions (see entire document, especially, page 1, first paragraph). One of the objects of Schott Glaswerke was to find a glass container for storing pharmaceutical or diagnostic solutions that remain largely inert with respect to the solutions (e.g., it was the desire of Schott Glaswerke to minimize the quantities of ions that leach out of the glass when storing the pharmaceutical or diagnostic solutions) (page 2, second complete paragraph). The problem of leaching of ions out of the glass was solved by coating the interior surface of the glass container with a layer of an SiO2 (page 2, fourth complete paragraph; page 3, first paragraph). The layer may be generated by means of plasma chemical vapor deposition (PCVD) (page 2, fourth, fifth,

and sixth complete paragraphs). In addition, Schott Glaswerke disclose that the composition of the glass of which the container is made is not critical, so long as the interior is coated with SiO2 (page 3, second, third, and fifth paragraphs; and page 4, 'Comparison' table and first paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Crane et al using the teachings of Yamaguchi et al, Schott Glaswerke, and Walther et al to coat the inner surface of a container that has a radiopharmaceutical (the radiopharmaceutical comprises a coordination complex of a metal and an organic ligand) with silica for the reasons below. (1) Yamaguchi et al, Schott Glaswerke, and Walther et al all disclose various advantages of using glass vials that are coated with silica. (2) Both Yamaguchi et al and Schott Glaswerke disclose advantages of using glass with silica coated interiors for radiopharmaceuticals. (3) A skilled artisan would have been motivated to use a silica coated glass interior in the invention of Crane et al in order to take advantage of one or all the advantages known in the art to be associated with silica coated interiors (i.e., avoid leaching of ions, provide a clear description of the container contents and the amounts thereof, etc.). (4) It would also be obvious to generate a kit comprising the radiopharmaceutical metal complex materials and a bacteriostat because Crane et al disclose that bacteriostats are added to diagnostic kits containing radiopharmaceutical metal complexes to inhibit the growth of bacteria either during its storage before use or after the kit is used to synthesize the radiopharmaceutical. (5) A skilled artisan in the art would be motivated to use PCVD to coat the interior surface with silica because Schott

Glaswerke and Walther et al disclose that it is well known in the art to use plasma chemical vapor deposition for coating glass surfaces with silica and the advantages of the process. In particular, Schott Glaswerke and Walther et al disclose that glass containers coated with PCVD are significantly more resistant to leaching.

Since Crane et al, Yamaguchi et al, and Schott Glaswerke are all directed to radiopharmaceuticals, the references may be considered to be within the same field of endeavor. Thus, the reference teachings are combinable. Furthermore, since, Schott Glaswerke, Yamaguchi et al, and Walther et al all are directed to silica coated glass interiors, the references may be considered to be within the same field of endeavor. Hence, those reference teachings are combinable.

(10) Response to Argument

Appellant's arguments submitted 5/9/2008 have been considered and are summarized below, but are deemed non-persuasive for the reasons set forth below.

Appellant asserts that since Crane et al do not give any description about a coating on the vial, the reference fails to provide motivation for improving the vial, let alone coating the inner surface with silica.

Appellant's argument is non-persuasive because obviousness and the motivation to modify an invention is based on the reference teachings as a whole. The fact that Crane et al do not state that their invention needs improvement does not negate the obviousness of modifying an invention wherein the prior art teaches various advantages of such a modification. The motivation to coat the interior surface of the container with

silica and the advantages associated with such action are set forth in the teachings of Yamaguchi et al, Schott Glaswerke, and Walther et al.

Appellant asserts that while Yamaguchi et al disclose silica coated vials, the reference is directed to preventing absorption of radiopharmaceutical materials such as thallium chloride. Hence, there is no description of using metal complexes as radiopharmaceuticals.

Appellant's argument is non-persuasive. because the use of metal complexes as radiopharmaceuticals is well known in the art as indicated by Crane et al. Thus, it is not clear why the advantages of using a silica coating interior container as set forth in Yamaguchi et al, Schott Glaswerke, and Walther et al would not hold true for metal complexes as well. Appellant has not presented any evidence as to why such advantages known in the art would not hold true for the invention of Crane et al. A skilled artisan would expect similar advantages using various radiopharmaceuticals as Schott Glaswerke illustrates that it is not the composition, but the silica coating that is critical (see page 4, 'Comparison' table and page 4, first paragraph). Likewise, in claim 5 (see page 3 of Yamaguchi et al), it is disclosed that the radiopharmaceutical preparation is characterized in that a radiopharmaceutical container in which the interior surface of a glass container is coated with silica is filled with an adsorbable radioactive material. Thus, the skilled artisan reading the claim would recognize that it is the coating, not the radiopharmaceutical that is critical. Hence, such an advantage would be expected with any radiopharmaceutical and the relevance of whether or not the radiopharmaceutical is a metal complex or not is not seen since this, according to the

prior art of record, would not change the advantages associated with the silica coated interior surface. Furthermore, Appellant is once again reminded that obviousness does not require absolute predictability, especially, since the prior art as a whole illustrates the advantages associated with silica coated vials and their use with radiopharmaceuticals.

Appellant asserts that Schott Glaswerke is silent about the use of radiopharmaceutical metal complexes.

Appellant's argument is non-persuasive. As stated previously, Schott Glaswerke illustrates that it is the silica coating interior, not the composition that is critical. The glass containers are coated on the inside with silica which provides the advantage of minimizing the amount of ions that are leached out of the glass into the solution. Schott Glaswerke discloses that their reference teachings apply to pharmaceutical and diagnostic solutions. A skilled artisan would recognize that radiopharmaceuticals are part of diagnostic agents and pharmaceutical agents. Hence, one of ordinary skill in the art would expect the advantages associated with the silica coated interiors to hold true for various pharmaceutical and diagnostic agents, such as radiopharmaceutical metal complexes, which are well known in the art (according to Crane et al), and within the broad scope of pharmaceutical and diagnostic agents.

Appellant asserts that there no teaching in Crane et al of leaching problems.

Appellant is reminded that the primary reference, Crane et al, need not state a specific problem in the reference that needs to be improved upon in order to be obvious over the an invention. The leaching problem is disclose in the art by, for example,

Schott Glaswerke, which discloses that if a container with a silica coated interior surface is used, the problem of leaching can be prevented. Hence, a skilled artisan would recognize the benefit would hold true for various pharmaceutical and diagnostic agents.

Appellant assets that Walther et al fail to refer to radiopharmaceutical metal complexes. Thus, there is no motivation to combine the reference teachings with those of Crane et al.

Appellant's arguments are non-persuasive because Walther et al disclose the advantages of silica coated vials with pharmaceuticals with the advantage of avoiding the disadvantages of the dealkylizing process of glass containers. Hence, one of ordinary skill in the art would recognize that that this advantage is only critical to the use of glass containers and not the pharmaceutical utilized. In addition, the skilled artisan would recognize that pharmaceuticals are commonly contained in glass vials and the teachings of Walther et al would be expected to hold true for any pharmaceutical in a glass vial or container. Neither Walther et al, Yamaguchi et al, nor Schott Glaswerke teach the criticality of the pharmaceutical agent, but all suggest that the silica coating, not the agent, is not critical to obtaining the benefits of using a container whose interior is silica coated.

Appellant asserts that Crane et al has many features to their invention. Thus, it is unclear why one would choose to improve the vials in the invention.

Appellant's argument is non-persuasive. First, obviousness is determined by the cited prior art as a whole. As a result, the fact that a reference discloses many features

is not a valid argument to obviate a teaching of an improvement to an aspect of an invention recognized in the art.

Appellant asserts that there is no motivation provided by the Examiner to address why one of ordinary skill in the art would choose the criteria of vials to improve Crane et al by coating the interior of the vial with silica.

Crane et al is relied upon to illustrate a general teaching that radiopharmaceuticals comprising metal complexes (diagnostic agents) contained in vials and kits thereof are will known in the art. However, the prior art discloses various advantages of placing pharmaceuticals, including radiopharmaceuticals, in container having a silica coated interior. Thus, there is nothing in the secondary references that would suggest that these advantages would not be gained with various pharmaceuticals.

Appellant asserts that an solubilization aid is essential to overcome absorption problems. Thus, one would not be motivated to look to solve the same problem using the teachings of the Yamaguchi et al.

Appellant's argument is found non-persuasive. Rather, a skilled artisan would recognize the motivation to combine Crane et al disclose and Yamaguchi et al based on the fact that both prior art documents realized the importance of the need to solve the same problem (e.g., absorption problems). Thus, just because Crane et al realized and chooses a means to address the problem does not mean that it is the end of the issue. Instead, a skilled artisan would be motivated to consider all various possible alternatives to circumvent a problem recognized in the art. Hence, since both Crane et al and

Yamaguchi et al both address the same problem, and are in the same field of endeavor, it would have been obvious to the skilled artisan to combine the teachings of the two references.

Appellant asserts that the combination of the references would teach away from the present invention.

Appellant's argument is non-persuasive. The secondary reference disclose various advantages of using silica coated containers and the type of pharmaceutical and radiopharmaceutical placed in the container is not critical to obtaining the advantages of the silica coating. Thus, the combination of references is not seen as a teaching away from the instant invention. In particular, there is nothing in the cited prior art to illustrate that one of ordinary skill would have been led away from the use of silica coated containers. The prior art does not set forth that solubilization aids are better than silica coated containers for solving absorption problems. Furthermore, Appellant's position ignores the other advantages taught by Yamaguchi et al, for example, that glass containers with a silica coated interior provide the advantage of accurate measuring of the radiopharmaceutical. In addition, Appellant's position ignores the advantage of Walther et al that it is known in the art to use glass containers that are coated with silica on the inner surface to avoid the disadvantage of the dealkalizing process of glass containers. Hence, the combination of references is not viewed as a teaching away from the instant invention.

It is duly noted that Appellant asserts that in accordance with 37 CFR 1.192(c)(7) that groups claims 1-5, 6-9, 10, and 11-14 do not stand or fall together. The Examiner

does not agree with Appellant's statement for the following reasons. Claims 13 and 14 depend on independent claim 10 while claim 12 depends on independent claim 11. Thus, claims should be grouped as (1-5), (6-9), (10, 13, and 14), and (11 and 12). However, even if the grouping of the claims was written correctly, the Examiner is not persuaded that the claims should not stand or fall together. First, it is noted that there is no explanation as to why the separately grouped claims do not stand or fall together. Secondly, the issue is whether or not it would be obvious to one of ordinary skill in the art to use silica coated vials for radiopharmaceuticals that contain a metal complex. The same issue applies to the kit claims as it is well known in the art to include radiopharmaceuticals in a kit. In addition, the kit does not incorporate any additional components. Also, it is noted that for independent claims 1, 6, and 10, an organic ligand which forms a coordination complex is always employed in a metal complex, as the term 'complex' is an art recognized term that defines coordination between an organic ligand and a metal. In addition, in regards to independent claim 11, a bacteriostat (see the discussion of Crane et al above) is commonly employed in radiopharmaceuticals to avoid contamination. Furthermore, as illustrated above, the only aspect of the instant invention lacking in Crane et al is the silica coated inner container surface which is provided by the secondary references. Hence, since the secondary references motivate one to use a silica coated container and disclose advantages of such containers for use with various pharmaceutical agents, one would be motivated to combine the reference teachings and arrive at a modified invention which contains overlapping subject matter with the instant invention.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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7/16/08
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